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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/575,618	07/17/2007	Mairread Kehoe-Whistance	34395-813.831	1340
21971 7590 10/13/2010 WILSON, SONSINI, GOODRICH & ROSATI 650 PAGE MILL ROAD PALO ALTO, CA 94304-1050				
EXAMINER				
DUFFY, BRADLEY				
ART UNIT		PAPER NUMBER		
1643				
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10/13/2010		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/575,618

Applicant(s)

KEHOE-WHISTANCE ET AL.

Examiner

BRADLEY DUFFY

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 August 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5-20, 22-33 and 38-47 is/are pending in the application.
- 4a) Of the above claim(s) 7-9,11,12,15,16,20,28,32,33,38-40,42-44 and 47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) See Continuation Sheet are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-940)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Continuation of Disposition of Claims: Claims subject to restriction and/or election requirement are 1,2,5,6,10,13,14,17-19,22-27,29-31,41,45 and 46.

DETAILED ACTION

1. The amendment filed August 2, 2010, is acknowledged and has been entered. Claims 1, 5, 6, 32, 33, 38 and 39 have been amended. Claims 4 and 21 have been canceled.

2. Claims 1, 2, 5-20, 22-33 and 38-47 are pending. Claims 7-9, 11, 12, 15, 16, 20, 28, 32, 33, 38-40, 42-44 and 47 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a non-elected invention or non-elected species of invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed December 10, 2009.

3. Claims 1, 2, 5, 6, 10, 13, 14, 17-19, 22-27, 29-31, 41, 45 and 46 are currently subject to a requirement to elect a species of invention, which has been necessitated by the amendment of claims 5 and 6 to depend from claim 1. Notably, these claims had previously been withdrawn from further consideration, but their amendment to depend from claim 1 has necessitated their current consideration.

Election/Restrictions

4. M.P.E.P. § 808.01(a) states: "If applicant presents species claims to more than one patentably distinct species of the invention after an Office action on only generic claims, with no restriction requirement, the Office may require the applicant to elect a single species for examination". See M.P.E.P. §§ 811.02 and 818.02(b).

Accordingly, because the elected invention was previously drawn to the immunogen having a MUC1 epitope, the claims previously recited a generic

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immunogen and the amendments to claims 1, 5 and 6 have presented patentably distinct species of epitopes further comprised in the immunogen, wherein said immunogen further comprises a carbohydrate epitope in claim 5 or wherein said immunogen further comprises STn in claim 6.

These species of the elected invention are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. In this case, the species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features. As set forth in Rule 13.2, "[t]he expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art".

In this case, the claimed epitopes lack the same or corresponding special technical features because as evidenced by the restriction requirement mailed September 10, 2009, original claim 1 lacked an inventive step over US 6,627,196 (Baughman et al, 9/03) for the reasons set forth in the restriction requirement. Furthermore, while the response filed August 2, 2010, appears to argue that amending claims 5 and 6 to require the Muc1 epitope of claim 4 causes the epitopes of claim 5 and 6 to be linked by the special technical feature of Claim 4, i.e., the MUC1 epitope, this is not found persuasive because as set forth in the previous office action the subject matter of claim 4 was rejected over the prior art. Therefore, it is apparent that the subject matter of claim 4 does not define a special technical feature. Accordingly, each immunogen of claim 5 or 6 is not linked by a special technical feature because the different species of immunogen are not linked to form a single general inventive concept under PCT Rule 13.1.

5. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a single invention to be examined and an election of the species of invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the

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claims encompassing the elected invention and the elected species of invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

6. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the

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product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brad Duffy whose telephone number is (571) 272-9935. The examiner can normally be reached at Monday through Friday from 7:00 AM to 4:30 PM, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Misook Yu,

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can be reached at (571) 272-0839. The official fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,
Brad Duffy
571-272-9935

/Stephen L. Rawlings/
Primary Examiner, Art Unit 1643

/bd/
Examiner, Art Unit 1643
October 8, 2010